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### **Remarks/Arguments:**

#### **I. Introduction**

Upon entry of the present amendment, claims 12-21 will be pending in this application. Claims 1-11 have been cancelled without prejudice in the interest of advancing the prosecution of this case. Claims 19-21 have been added to more fully claim a particle that can be used in connection with the methods of this application. No new matter has been added. Based on the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

#### **II. Claim 18**

The Examiner has objected to claim 18 as being directed to an independent invention. This objection is unexplained and unclear. Claim 18 depends from claim 17 which recites a method for delivering insulin using the claimed particle. Claim 18 further defines that the particle has polyethylene glycol ("PEG") associated with its core. The fact that claim 18 depends from claim 17 necessarily means that the method of claim 18 is used to deliver insulin, the particle simply further comprises PEG. Because of this, Applicants do not understand the Examiner's statement that "any methods of utilizing them are patentably distinct." Accordingly, claim 18 should be rejoined and examiner in this application.

#### **III. 35 U.S.C. § 103**

The Examiner has rejected claims 12-17 under 35 U.S.C. § 103(a) as being unpatentable over Bell et al. (U.S. Patent No. 6,355,271) in view of Corrigan et al. (WO 99/03451). The Examiner's position is that it would have been obvious for one of ordinary skill in the art to use the casein disclosed by Corrigan et al. in conjunction with the calcium

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phosphate particles disclosed by Bell et al. The examiner has noted, however, that the rejection can be overcome by showing either that (1) the Bell patent is not an invention "by another" or that (2) the Bell patent is not available as prior art under 103(c) in a rejection under 103(a).

Without acquiescing to the Examiner's rejections, Applicants submit with this response a declaration from Dr. Bell, who is an inventor of the Bell et al. patent, as well as an inventor of the present application. This declaration makes it clear that (1) Dr. Bell is the same inventor of the Bell patent as well as the invention claimed in the present application; in other words, the Bell patent is not an invention "by another" under 102(e)<sup>1</sup> and/or (2) that both inventions are commonly assigned to BioSante Pharmaceuticals (in the event that the presence of other inventors invokes 103(c)).<sup>2</sup> Accordingly, Applicants respectfully request that this rejection be withdrawn.

#### IV. New claims 19-21

Applicants have also presented new claims 19-21, which recite the features of the particle that can be used in connection with the claimed method. Because these claims mirror

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<sup>1</sup> 102(e) - A person shall be entitled to a patent unless the invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

<sup>2</sup> 103(c): "Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."


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method claim 12, no new search is needed, and their presentation does not present an undue burden on the examiner.

### CONCLUSION

For at least the above reasons, Applicant respectfully requests allowance of claims 12-21 and issuance of a patent containing these claims in due course. If there remain any additional issues to be addressed, the Examiner is invited to contact the undersigned attorney at 404.815.6147.

Respectfully submitted,



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